

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Kasper et al. )  
)  
Date Filed: August 3, 1999 )  
)  
Serial No: 09/368,010 ) Group Art Unit: 1641  
)  
Title: MONOCLONAL ANTIBODIES FOR ) Examiner: M. Ceperley  
TACROLIMUS AND IMMUNOASSAY )  
METHODS FOR TACROLIMUS )  
)  
Atty. Docket No.: BEH 7443 )

**RESPONSE TO RESTRICTION REQUIREMENT**

Ass't Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

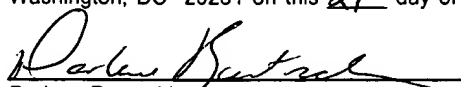
In response to the office action mailed November 1, 2000, Applicants elect to prosecute Group IV. Applicants make this election with traverse.

The present case contains 82 claims. Claims 1-63 are directed to monoclonal antibodies to tacrolimus, hybridomas producing a monoclonal antibody to tacrolimus, a single chain recombinant antibody including therein the variable regions of an antibody to tacrolimus, antibody to tacrolimus conjugated to a label, a method of detecting or determining tacrolimus using an antibody to tacrolimus, and test kits containing antibody to tacrolimus. Claims 64-82 concern derivatives of tacrolimus and conjugates of such derivatives as well as methods for derivatizing tacrolimus and for producing conjugates.

The Examiner has imposed a 14-way restriction requirement. For example, treated as separate inventions are Groups III and IV. Both groups are drawn to a monoclonal antibody produced by fusion of cells from a mammal immunized with tacrolimus derivatized with a carboxymethyl oxime moiety at a carbon atom in the non-binding domain of tacrolimus. Group IV specifies that the carboxymethyl oxime moiety is at carbon atom 22. (Carbon atom 22 is in the non-binding domain of tacrolimus.) Similarly, the distinction between Group V and Group VI is that in Group V, the derivatization of tacrolimus is via a carboxymethyl oxime moiety at a carbon atom in the non-binding domain, and in Group VI the hapten is derivatized with an oxime moiety at carbon atom 22.

.....  
CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service as First Class Mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on this 21<sup>st</sup> day of December, 2000.

  
Darlene Rentschler

Thus, Applicants respectfully submit that the inventions of Claims 1-63 are not independent within the meaning of MPEP 806.04 and 808.01 ("this situation, except for species, is but rarely presented, since persons will seldom file an application containing disclosures of independent things.") The claims concern antibodies to tacrolimus which are used in immunoassays.

Moreover, as set forth in the MPEP, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." Applicants respectfully submit that a search for claims 1-63 will not impose a serious burden and such claims should all be included in one group and prosecuted in one application.

Applicants note that the Examiner had previously contacted Applicants' attorney on or about November 18, 1999 with regard to restriction of claims in this application. In the November 18 restriction requirement, the Examiner identified seven groups of claims and required election of one of such groups. Applicants responded by facsimile, electing prosecution of Group I, Claims 1-63, drawn to antibodies and their use in immunoassays. A copy of Applicants' response and the confirmatory sheet showing the facsimile transmission, are enclosed herewith.

Applicants respectfully request that the restriction requirement as to Claims 1-63 be withdrawn and that prosecution proceed on the merits.

Respectfully submitted,

  
Lois K. Ruszala

Registration No. 39,074  
Attorney for Applicants

DADE BEHRING INC.  
1717 Deerfield Rd, PO Box 778  
Deerfield, IL 60015-0778  
847-267-5364